

Ending the U.S. government's war on medical marijuana research

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INTRODUCTION



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The federal government is stifling medical research in a rapidly transforming area of public policy that has consequences for public health and public safety. As medical marijuana becomes increasingly accessible in state-regulated, legal markets, and as others self-medicate in jurisdictions that do not allow the medical use of cannabis, it is increasingly important that the scientific community conduct research on this substance. However, statutory, regulatory, bureaucratic, and cultural barriers have paralyzed science and threatened the integrity of research freedom in this area.

It is time for the federal government to recognize the serious public policy risks born from limited medical, public health, and pharmaceutical research into cannabis and its use. People are using cannabis nationwide to treat a variety of ailments. Doctors in dozens of states are recommending the use of this product as a pseudo-pharmaceutical intervention. The elderly, veterans, children, and people from every demographic group in the nation claim that the use of cannabis assists in the treatment of their medical conditions. Despite this, there is limited scientific research on the efficacy of this product overall or by condition or dosage, on interactions, on composition, on side effects, or much of anything else.

Rescheduling will not suddenly legalize marijuana. It would not even solve the policy disjunction that exists between states and the federal government on the question of marijuana legality—or even value. Nor does rescheduling mean that medical marijuana will line the shelves of commercial or hospital pharmacies.

Observational studies exist, as do some small scale, rigorous, double-blind, clinical studies. However, the U.S. government has held back the medical community's ability to conduct the type of research

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that the scientific community considers the experimental gold standard in guiding medical practice. The use of cannabis for medical treatment is happening in states based largely on anecdotal evidence or limited science. In many cases, patients and doctors operate according to a learn-as-you-go approach—a situation that is inexcusably the fault of federal policies failing to keep pace with changing societal views and state-level legal landscapes.

Beyond interfering with the relationship between doctor and patient, the current policy stance toward medical marijuana and its research presents additional policy and practical challenges. Each day, patients, practitioners, hospitals, universities, and other public health professionals face tremendous questions about how federal drug policy can affect the practice of medicine and the daily operation of medical research and enterprise. The resulting legal gray area means that from day to day, state to state, practitioner to practitioner and even case to case the delivery of health care in the U.S. is interrupted and complicated by inconsistent and often contradictory policies.

The irony of the issue is that it has very little to do with marijuana. This policy problem involves medical research and scientific freedom. This same conversation would be had if such barriers hindered the study of morphine or diazepam or Propofol or any other drug. Yet, of all the controlled substances that the federal government regulates, cannabis is treated in a unique manner in ways that specifically impede research.

Numerous proposals exist that seek to ameliorate some of these challenges. Some proposals are meaningful and would make for substantive changes that advance medical research. Others are narrow-sighted, misunderstood, misapplied, or fail to provide the type of large-scale change necessary to achieve reformers' desired goals. Before a research-oriented reform of medical marijuana policy can be advanced, there must be a more complete understanding of the political and policy realities surrounding this issue.

This paper explores the specific federal government policies that limit medical marijuana research. It details the consequences of those policies for the medical community and for public policy. The paper examines some of the proposed solutions to this problem and assesses their strengths and shortcomings. It offers a more comprehensive policy reform that will liberate the medical community in its pursuit of research into marijuana. Finally, the paper engages the politics of this issue, detailing the risks and rewards of reform.

I. WHY RESCHEDULING MARIJUANA ONLY DOES SO MUCH

HOW RESCHEDULING WORKS

As we have written before, rescheduling is not a simple process for the executive branch.¹ A petition, initiated from an outside party or from within the administration, must be reviewed first by the Department of Health and Human Services (via the Food and Drug Administration [FDA]), and then by the attorney general, who typically delegates that task to the Drug Enforcement Administration (DEA), on eight key factors to determine if there is a scientifically

¹ <http://www.brookings.edu/blogs/fixgov/posts/2015/02/13-how-to-reschedule-marijuana-hudak-wallack>

accepted medical use for the drug, its potential for and history of abuse, and any risk to the public health.² Historically, four petitions that have been initiated to reschedule marijuana or remove it from the schedules entirely have been denied or stalled by DEA with disposition times ranging from five to more than 20 years.³ [See table in appendix]

Congressional rescheduling of a drug is a much simpler process. Congress can amend the Controlled Substances Act (CSA) to move cannabis to Schedule II (or to another schedule or off the schedules entirely) without going through the same administrative process that binds the attorney general. Many bills have been introduced, the first in 1981, that would either move marijuana to Schedule II or remove it from the schedules entirely. Each proposal has died in committee. The recently-introduced CARERS Act (Compassionate Access, Research Expansion, and Respect States Act of 2015) would also move marijuana to Schedule II and remove cannabidiol (CBD) oil from the schedules (among other reforms). This legislation has garnered more attention than previous efforts in Congress. While it may not be politically expedient for all members, congressional rescheduling is certainly more straightforward than the executive branch option.

THE HISTORY OF RESCHEDULING

Of the four petitions initiated to reschedule marijuana, three have been denied by DEA, and one (submitted by then- Governors Christine Gregoire (WA) and Lincoln Chaffee (RI) in 2011) is still under review. The first petition, initiated by NORML (National Organization for the Reform of Marijuana Laws) in 1972, was not acted upon by DEA until 1986, after three different rulings in federal courts required DEA to review the petition. It was ultimately denied in 1994, 22 years after its submission. The second petition was initiated in 1995 and denied in 2001, and the third, submitted in 2002, was denied in 2011, despite the multitude of states with medical marijuana programs by that time.⁴

Moving a drug between schedules has also been an uncommon occurrence since the CSA was passed in 1970. Some noteworthy cases of rescheduling include Marinol (now Schedule III) and Hydrocodone Combination Products (HCPs), which are now Schedule II. Marinol—the trade name for the synthetic cannabinoid dronabinol—was first moved from Schedule I to II in 1985, and then from II to III in 1999.⁵ In 2014, hydrocodone combination products, known as HCPs, were moved in the opposite direction, from III to II, with DEA citing public safety and prescription drug abuse as reasons for “upscheduling” HCPs.⁶ Hydrocodone and Oxycodone have always been Schedule II, but their combination products were Schedule III until October 6, 2014. It’s worth noting that the petition to review the status of HCPs was first brought in 2004, so even absent the political heat that accompanies marijuana politics, the full review and rulemaking process for HCPs took 10 years.

In addition, DEA has administrative authority to remove a drug from the schedules entirely, following the review process, as it did in 2014 with Naloxegol, a drug used in the treatment of medication-induced digestive issues. In total, DEA has rescheduled drugs 39 times in its 40+ years of existence.⁷ However, there have been only five cases of DEA moving a Schedule I drug to Schedule II, and only two cases of DEA removing a Schedule I drug from the scheduled list entirely.⁸

2 21 U.S.C 811(a)-(c)

3 https://www.drugpolicy.org/sites/default/files/DPA-MAPS_DEA_Science_Final.pdf

4 Federal Register Volume 76, Number 131 (Friday, July 8, 2011) “Denial of petition to initiate proceedings to reschedule marijuana”

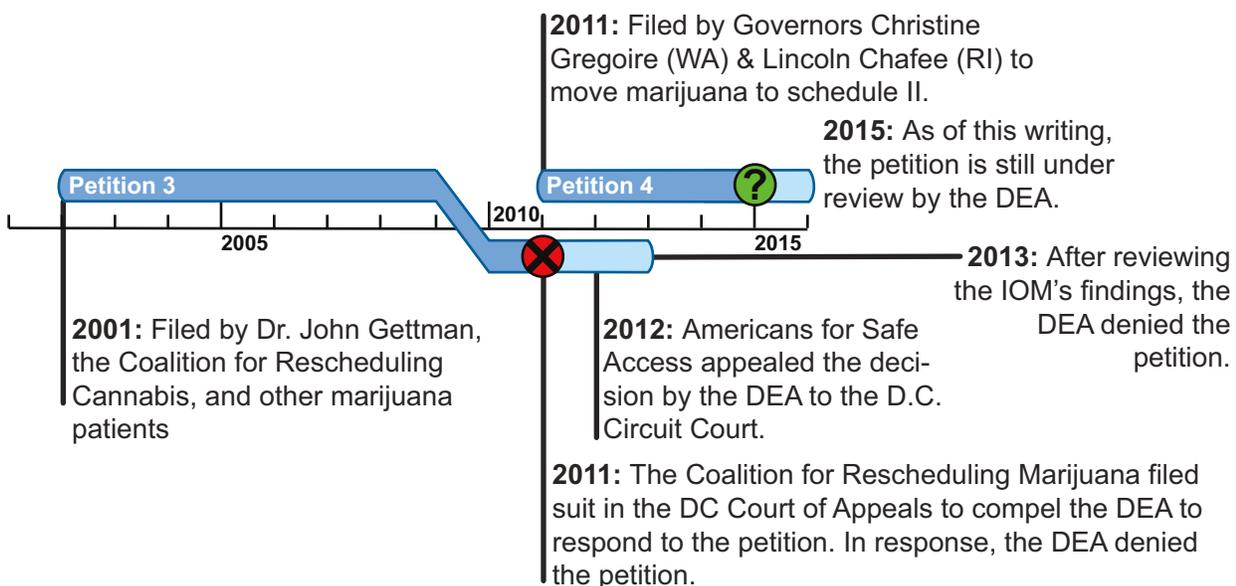
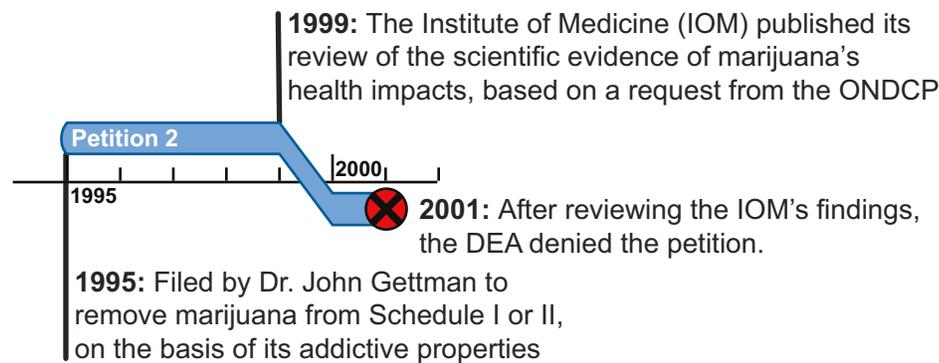
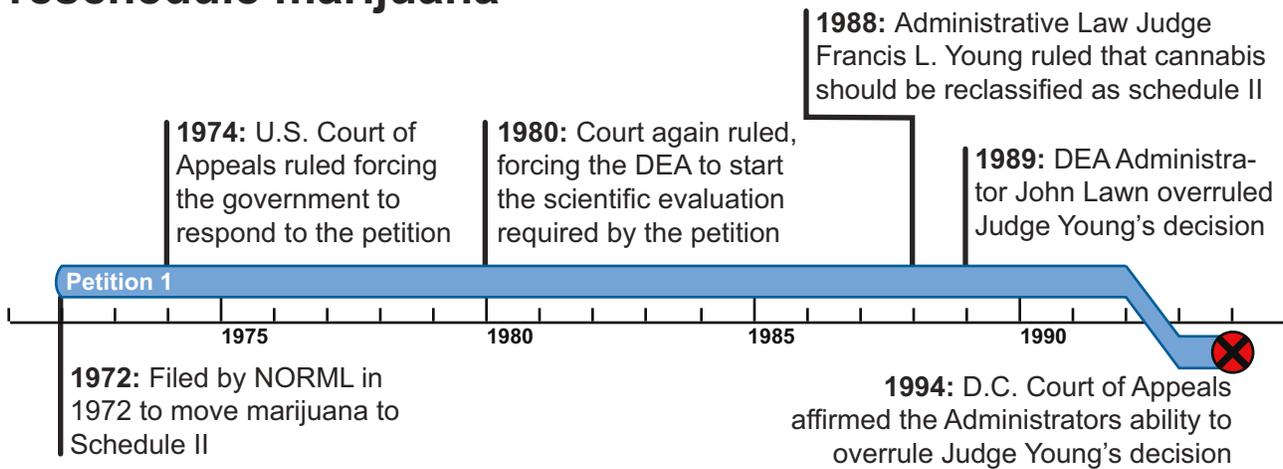
5 Federal Register Volume 64, Number 127 (Friday, July 2, 1999)

6 Federal Register Vol. 79, No. 163 (Friday, August 22, 2014)

7 <http://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>

8 Ibid

Timeline of petitions to reschedule marijuana



WHAT RESCHEDULING WOULD DO

Rescheduling a drug like cannabis is a challenging political and administrative process, but if achieved, it would have significant effects on drug policy beyond a simple recategorizing of the substance.⁹ Federal recognition of an accepted medical use for marijuana would be an important signal to the medical and policy communities that this avenue of research is supported—or at least that it is not something the government is actively skeptical of. David Nutt, David Nichols, and Leslie King write in their recent article that the Schedule I status of marijuana discourages researchers from even applying to conduct studies, whether or not they would ultimately be approved.¹⁰

Nutt, et al describe risk aversion among institutional review boards, and a culture predisposed to avoid marijuana research permeates. Universities may worry how donors, parents or trustees may react to research programs that advance claims of marijuana’s benefits.¹¹ There have also been recent, high-profile fallings out between universities and research faculty studying marijuana. The National Institute on Drug Abuse (NIDA) is currently funding 28 projects on marijuana, of which 13 are on human subjects (and nine use synthetic cannabis).¹² Caulkins, et al (2012) cites data from 1990-2011 in which 21 double-blind, clinical (Class 1) studies were published involving the administration of cannabis plant material (through 2015, that number is 27).¹³

A search of medical journals often turns up numerous studies that involve “marijuana,” “cannabis,” or “cannabinoids.” However, the number of studies that focus on the administration of cannabis in human subjects is limited, and that number is further reduced when looking at research conducted in the United States. Finally, until 2015, the NIDA-contracted marijuana research farm in Mississippi produced only 20 kilograms of marijuana annually, severely limiting the ability of a large number of researchers to perform large-scale, Class 1 studies.

List of drugs moved from Schedule I to Schedule II

Drug name	Drug description	Original schedule	Moved to	Date	Reasoning
Alfentanil	Short-acting opioid analgesic	I	II	1987	The DEA action followed FDA approval of a new drug application for alfentanil.
Marinol*	Synthetic cannabinoid in gelatin capsules	I	II	1987	The DEA rescheduled Marinol after the FDA approved the drug for treatment of nausea in cancer patients.**
Etorphine Hydrochloride	Opioid analgesic strictly for veterinary use.	I	II	1974	The DEA rescheduled etorphine after FDA approval for the use of the drug for the immobilization of wild and exotic animals.
Levo-Alphaacetylmethadol (LAAM)	Synthetic opioid similar to methadone.	I	II	1993	The DEA rescheduled LAAM following a letter from the HHS Secretary that recommended a transfer to Schedule II.
Sufentanil	Synthetic opioid analgesic	I	II	1984	The DEA rescheduled Sufentanil following a letter from the HHS Secretary that recommended a transfer to Schedule II upon the drug being approved for marketing.

Source is the Federal Register unless otherwise noted. A list of rescheduling actions is available at: <http://www.deadiversion.usdoj.gov/schedules/orangebook/orangebook.pdf>
 *Marinol was subsequently moved to Schedule III in 1999.
 **http://www.deadiversion.usdoj.gov/fed_regs/rules/1999/fr0702.htm

⁹ Beyond the effect on medical research, rescheduling cannabis could have implications for other areas of policy. For example if rescheduled to III, IV, V, or de-scheduled, existing marijuana enterprises could see substantial tax benefits. However, while such issues are important, they are beyond the scope of this paper.

¹⁰ Nutt, David J., Leslie A. King, and David E. Nichols. “Effects of Schedule I drug laws on neuroscience research and treatment innovation.” *Nature Reviews Neuroscience* 14, no. 8 (2013): 577-585.

¹¹ <http://www.newsweek.com/why-its-hard-do-marijuana-research-69753>

¹² <http://www.drugabuse.gov/drugs-abuse/marijuana/nida-research-therapeutic-benefits-cannabis-cannabinoids> . NIDA lists another 16 studies that use NIDA-supplied products, but are independently funded.

¹³ Caulkins, Jonathan P., Angela Hawken, Beau Kilmer, and Mark Kleiman. 2012. *Marijuana Legalization: What Everyone Needs to Know*. Oxford University Press.

The importance of culture and perception should not be overlooked in this area. Ultimately, researchers, medical professionals, universities, and hospitals are staking their own reputations on the output of their research endeavors, not to mention competing for small pools of National Institutes of Health (NIH) and private funding. Moving marijuana from Schedule I to Schedule II would signal to the medical community that FDA and NIH are ready to take medical marijuana research seriously, and help overcome a government-sponsored chilling effect on research that manifests in direct and indirect ways.

Rescheduling would have substantive effects beyond changing perceptions. DEA, FDA, and state law all require levels of licensing and registration for conducting research with Schedule I drugs. Researchers hoping to obtain approval for research with marijuana (or any Schedule I drug for that matter) go through a multi-agency registration and review process. For any research with marijuana, researchers must undergo the FDA's Investigational New Drug (IND) application, and NIH-funded projects must also undergo an additional, three-step NIH review. Researchers then obtain a DEA registration for possessing marijuana for research (this is also true of any Schedule I drug). Unlike other Schedule I drugs however, researchers then submit their proposal and request for study drugs to NIDA for review and to approve the supply of the drugs they need.¹⁴ Both the DEA-mandated NIDA monopoly on research marijuana and DEA registration represent hurdles to marijuana research that are not present for Schedule II drugs—or even other Schedule I drugs.

Under DEA's licensing system, there are categories of activities for which a medical professional must register in order to use any scheduled drugs (I-V). For example, there are independent registrations for manufacturing, distribution, and research. The key distinction between Schedules I and II, for the purposes of research, is the “Dispensing and Instructing license” available for hospitals, pharmacies, practitioners, etc., for drugs in Schedules II-V, but not Schedule I, as those drugs have no “accepted medical use.”¹⁵ This is commonly called the “practitioner” registration, and covers the entire medical practice, not just an individual trial, and is renewed every three years. Importantly, the practitioner license allows for practitioners to conduct clinical trials with drugs in schedules II-V, as long as they are “coincident” with their usual practice. A separate DEA “researcher” registration is required for schedules II-V if the clinical trial occurs “outside” the practitioner’s regular practice, which in practice seems to mean at a different location than the normal practice.¹⁶

Clinical trials with any Schedule I substance, however, always require a researcher registration, and is subject to more stringent controls and reporting requirements than either the practitioner registration or the Schedule II-V researcher registration. Thus, rescheduling marijuana from I to II would remove a significant barrier to research in the form of more relaxed registration requirements for practitioners.¹⁷

There are however, a few caveats. The practitioner license would not, for example, allow practitioners to conduct clinical trials with the marijuana currently available in state-legal recreational or medical marijuana programs. The

¹⁴ NIDA, under a mandate from DEA, maintains a monopoly over marijuana used in federal government-sponsored research. All researchers must use product grown at a grow facility at the University of Mississippi.

¹⁵ 21 USC §1301.13

¹⁶ DEA Practitioner’s Manual (2006) http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf; Personal communication.

¹⁷ There exist additional registration requirements for the importing and exporting of controlled substances. For such purposes, the statutory requirements for the import and export of Schedule I and II substances are much more limiting than the rules for Schedule III, IV, and V substances (i.e., registration for the former is restricted to the specific substance in the application; compassion registration for the latter applies to the category of substances) 21 USC 958

DEA still licenses manufacturers for all controlled substances (I-V) and enforces production quotas on schedules I and II.¹⁸

In addition, state requirements also limit who can be licensed to handle scheduled substances. After the passage of the CSA in 1970, many states adopted the Uniform Controlled Substances Act (Uniform Act).¹⁹ The Uniform Act is a set of guidance issued by the National Conference of Commissioners on Uniform State Laws that encourages “uniformity between the laws of the several States and those of the federal government.”²⁰ In the context of drugs, the “main objective of this Uniform Act is to continue a coordinated and codified system of drug control.”²¹ In the context of drug policy, nearly every state has adopted some or all of the Uniform Act, including policy over drug scheduling.²²

For states that have adopted rescheduling policy of the Uniform Act, the impact of federal rescheduling is quite straightforward. When DEA moves a drug between schedules (either by routine or emergency scheduling), the Uniform Act requires the state agency to reschedule the drug accordingly, unless an objection is made, typically within 30 days.²³ In that case, the state agency would follow a scheduling review similar to the federal administrative process. In most cases these state laws have followed the federal scheduling, but states can be more stringent. In the case where state law is more stringent than federal law, DEA requires the more stringent procedures be followed.²⁴ If the federal government rescheduled marijuana, many states would follow suit, but states could also choose to impose more stringent restrictions on researchers using marijuana for medical research. In states that have already legalized medical marijuana, federal rescheduling would have little impact at the state level. But given state-level discretion, some states could choose to maintain strict control on marijuana, creating a patchwork of varying research regulations across the U.S.

Contrary to common misconceptions, reclassifying cannabis from Schedule I to Schedule II would not open the floodgates of dramatic change.

WHAT RESCHEDULING WOULD NOT DO

Contrary to common misconceptions, reclassifying cannabis from Schedule I to Schedule II would not open the floodgates of dramatic change. It would not signify the drug as “safe” or really make any subjective judgment about the dangers of taking it. In fact, the distinction between Schedule I and Schedule II centers mainly on a substance’s medical value. Schedule I drugs have “no currently accepted medical use in treatment in the United States.” Schedule II drugs “have currently accepted medical use in treatment in the United States...with severe restrictions.” Substances under both schedules are believed to have “high potential for abuse.”

¹⁸ DEA, CFR 1301.13, and the first clinical research manual

¹⁹ <http://www.uniformlaws.org/ActSummary.aspx?title=Controlled%20Substances%20Act>; http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf

²⁰ National Conference of Commissioners on Uniform State Laws. “Uniform Controlled Substances Act.” 1994. Chicago. The Uniform Controlled Substances Act was initially issued in 1970 and was updated in 1984, 1986, 1988, 1990, and 1994.

²¹ Ibid.

²² For a detailed discussion on how states have adopted the details of the Uniform Act, differences and distinctions among states, and how federal-state policies are implemented see the National Criminal Justice Association’s “A Guide to State Controlled Substances Acts,” revised January 1999.

²³ http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf, pg 14

²⁴ <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm>

In fact, those who fear that rescheduling cannabis from I to II would signal something inherently positive about the substance are misguided. A review of the types of drugs listed under Schedule II make clear this point. Schedule II contains some mainstream medications such as Vicodin and Ritalin. However, Schedule II also contains cocaine, methamphetamine and oxycodone—drugs universally believed to be risky and dangerous.

[I]f policy makers at the federal and/or state levels opt to proceed with reform, they should do so in a forward-thinking, comprehensive, precise, and well-informed manner that considers both the unintended and intended consequences of reform.

Rescheduling would designate cannabis as possibly having “accepted medical use.” The current Schedule I designation of cannabis, in conjunction with the numerous additional, and unique institutional rules regulating the substance, creates a circular policy trap that hinders scientific research. Research on the medical value of cannabis is limited by the Schedule I designation

of cannabis, which asserts that the substance has no medicinal value. However, the scientific community is unsure whether marijuana has medicinal value because of a lack of research.

Rescheduling will not suddenly legalize marijuana. It would not even solve the policy disjunction that exists between states and the federal government on the question of marijuana legality—or even value. Nor does rescheduling mean that medical marijuana will line the shelves of commercial or hospital pharmacies. Before the federal government would sanction marijuana as a substance both with medical value and prescribed use, it would need rigorous clinical testing through FDA—an arduous and uncertain process that is already heavily regulated.

Other concerns exist that rescheduling marijuana would throw open the doors for pharmaceutical corporations to begin research on cannabis. There is no doubt that the opportunity would be present for companies to engage in such research, conduct clinical trials, file New Drug Applications (NDAs), and assert themselves as a force in the market. Federal reform that gives cannabis a pharmacological designation would come with a chance that Big Pharma would seek to capitalize on market opportunities. However, the pharmaceutical industry’s relationship to (medical) cannabis is quite different than it is for myriad other medical products. The industry has largely resisted research into the product and in its place, numerous small and medium sized cannabis-centered enterprises have filled that void.

If, after rescheduling, pharmaceutical companies chose to expand research into medical cannabis, they would be entering a market with numerous existing producers and mature consumer (patient) tastes. What’s more, concerns over Big Pharma entering the market and acquiring existing portions of the medical marijuana industry in states in which it is currently legal are overstated. Many states through constitutional, statutory, and/or regulatory means restrict the ability of out-of-state companies to acquire enterprises. Some states have restrictions on the sale or transfer of businesses and operating licenses. This provides some safeguards against rescheduled cannabis segueing into “Big Marijuana.”²⁵ What results is a regulatory public choice opportunity. If the public and elected officials are concerned about Big Pharma dominating medical marijuana research and production, policy options exist to impose limits on

25 To be clear, Big Marijuana could come in the form of existing pharmaceutical companies entering the market and dominating it or it could occur with other businesses entering the market and dominating it. The idea of Big Marijuana is simply a small group of corporate players playing an outsized market role in a way that crowds out competition.

that behavior. It is not to say such a situation is impossible, and the manner in which states respond to changing legal and policy realities (as well as interest group environments) will have profound influence on the likelihood of Big Marijuana exploding onto the scene.

Additionally, DEA enforces production quotas for both Schedule I and Schedule II substances, even when produced by non-NIDA manufacturers.²⁶ One way to regulate against the problem of “Big Marijuana” is to use the DEA licensing scheme already in place to slowly ramp up production. Moving marijuana from Schedule I to II would not automatically “open the floodgates” for big drug manufacturers, because DEA still has licensing and quota controls over the production of Schedule II drugs. The DEA administrator could choose to slowly increase the quota for marijuana in Schedule II over time, in response to research needs, and eventually, medical use. Congress also has the ability to amend the CSA to encourage more—or less—production of a scheduled substance. The CARERS Act, for example, would require DEA to license three producers of marijuana for medical research, to overcome the NIDA monopoly. If Congress separately rescheduled marijuana, they could also choose to impose a cap on the number of facilities that are licensed to produce marijuana.

Concerns over Big Marijuana as a market concept are legitimate. What those concerns suggest is not that reform is necessarily a bad idea. Instead, it indicates that if policy makers at the federal and/or state levels opt to proceed with reform, they should do so in a forward-thinking, comprehensive, precise, and well-informed manner that considers both the unintended and intended consequences of reform.

II. COMPREHENSIVE SOLUTIONS TO EXPAND MEDICAL MARIJUANA RESEARCH

Although the most direct option for expanding medical marijuana research would begin with congressional rescheduling, there are many executive actions, independent of Congress, that would facilitate medical marijuana research. Indeed, even if Congress rescheduled marijuana tomorrow, many of these administrative revisions would likely still be necessary to expand research opportunities fully.

ENDING THE DEA-MANDATED NIDA MONOPOLY

One continuous source of frustration for researchers is the single-producer, DEA-mandated NIDA monopoly on the production of marijuana for research.²⁷ Currently, NIDA contracts with the University of Mississippi—and only the University of Mississippi—to produce marijuana for federally-approved studies. Because of this monopoly, research-grade drugs that meet researchers’ specifications often take years to acquire, if they are produced at all. This creates a serious limitation on marijuana research, more so than for any other Schedule I substance.²⁸

²⁶ 21 U.S.C. 826 and Federal Register, Vol. 79, No. 173 (Monday, September 8, 2014)

²⁷ Previously the required, redundant Public Health Service review of all research applications involving marijuana (a procedure used for no other controlled substance) created a similar frustration. On June 23, 2015, the Obama administration unilaterally ended the requirement that PHS review such applications. <https://www.federalregister.gov/articles/2015/06/23/2015-15479/announcement-of-revision-to-the-department-of-health-and-human-services-guidance-on-procedures-for>

²⁸ NIDA has recently begun making low-THC, high-CBD strains of marijuana available in their online catalogue for researchers in response to demand from the community to conduct research into CBD as a treatment for epilepsy. Despite this nod to researchers, many still argue the NIDA monopoly is an undue burden on medical research. <http://www.leafscience.com/2014/03/25/u-s-federal-marijuana-farm-offer-new-strains/>

The DEA grants one license to the University of Mississippi to produce marijuana for research, which is funded through a NIDA contract, and overseen by NIDA. The DEA justifies this monopoly with the U.N. Single Convention on Narcotic Drugs' requirement that production of scheduled substances for research purposes be overseen by a government entity.²⁹ However, as is detailed below, DEA does have the freedom and capacity to expand the number of grow operations that supply marijuana for government-approved research endeavors. In fact, some argue DEA has the legal *requirement* to do so. Removing the NIDA monopoly could be accomplished by Congress (and is in fact a provision included in the CARERS Act) but could also be done administratively without action by Congress. Because the NIDA monopoly is based simply on DEA's interpretation of the U.N. Single Convention on Narcotics, this interpretation could be changed by DEA at the direction of the president. In 2007, DEA administrative law judge Mary Ellen Bittner ruled that DEA's rejection of another researcher's request to grow marijuana for research at the University of Massachusetts was improper and that granting the application would "not be inconsistent with the Single Convention."³⁰ The DEA administrator, Michele Leonhart, subsequently rejected this ruling, but a different administrator with a different perspective could license multiple producers.³¹

Indeed, DEA currently licenses multiple, privately-funded labs for the production of Schedule I substances *besides* marijuana for medical research.³² It would not necessarily be inconsistent with DEA's own policy around Schedule I drugs to license more than one producer for research-grade marijuana. In fact, the section of the CSA that licenses "bulk" producers of Schedule I and II drugs reads, "In order to provide adequate competition, the [DEA] Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply."³³

The DEA is certainly justified in arguing the NIDA monopoly is an effective way of limiting diversion of marijuana, but the single-producer monopoly is not *required* by statute or by UN Conventions.³⁴ In fact, if the Single Convention required that Schedule I substances be manufactured by a single entity, the U.S. would be in violation of the Convention in the manufacture of other Schedule I substances. Indeed, even NIDA officials recognize the impediment to research that their monopoly creates. At a Senate Drug Caucus hearing on June 24, 2015, NIDA Director Nora Volkow stated that she believes licensing multiple producers of marijuana for medical testing would be beneficial.³⁵

Moreover, many medical marijuana researchers argue that the NIDA monopoly is failing to meet its statutory mandate under CSA. By statute, the government must license "a number of establishments which can provide an adequate and uninterrupted supply of the stances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes."³⁶ Considering DEA has managed to license multiple producers for at least some other Schedule I drugs, it could certainly formulate a policy to license multiple producers of marijuana while still maintaining adequate controls—it has simply chosen not to. On the other hand, NIDA has planned to increase

²⁹ https://www.unodc.org/pdf/convention_1961_en.pdf

³⁰ In the matter of Lyle E. Craker, Docket No. 05-16, Drug Enforcement Administration, February 12, 2007.

³¹ Federal Register Vol. 74, No. 9 (Wednesday, January 14, 2009)

³² DEA, 2007.

³³ 21 C.F.F section 1301.33(b)

³⁴ The U.N. Conventions simply require that cannabis production be regulated by one or more government agencies and that those agencies license and regulate producers of the substances, without making reference to an explicit number of producers. In fact, the language specifically uses the plural "cultivators" when discussing the requirements around manufacture (See Articles 23 & 28).

³⁵ <http://www.drugcaucus.senate.gov/content/drug-caucus-hearing-barriers-cannabidiol-research-0> (1:06:18)

³⁶ 21 USC 823(a)(1)

its production of marijuana, specifically in response to research requests, from 21 kilograms to 640 kilograms.³⁷ However, many argue that the quantity and diversity of marijuana produced by NIDA will be lacking relative to what multiple providers would offer.

With the recent removal of the Public Health Service (PHS) review,³⁸ more policymakers are beginning to think that, while full legalization may not be responsible at the moment, marijuana deserves at least to be studied with the same availability as heroin or LSD. Removing NIDA's single-producer monopoly on research-grade marijuana would not even be “special treatment” for marijuana, but would simply bring marijuana policy in line with DEA's treatment of many other Schedule I drugs.

There are a variety of pathways out of the single-producer NIDA monopoly. The DEA could follow its practice with other Schedule I substances and license other private labs for the production of research-grade marijuana. DEA could also hypothetically partner with medical marijuana states to produce consistent and reliable strains like those already being dispensed. In fact, many medical states are implementing policies that require marijuana producers to follow GMP (Good Manufacturing Practices) standards in the production of pharmaceutical-grade cannabis. Such policies are consistent with those standards used by the University of Mississippi facility. The American Herbal Products Association's Cannabis Committee offers recommendations for standards for dispensing, laboratory operations, cultivation, manufacturing, labeling, packaging, and other practices. The expansion of the research-grade marijuana supply chain to other universities or existing state-run facilities could be a safe, useful, and reliable remedy to supplant the existing federal program.

These options would be hypothetically available without rescheduling marijuana from I to II, but could certainly come in conjunction with rescheduling. The proper reform would not remove NIDA or other agencies of the federal government from regulating the production of research grade marijuana—such a move would violate international agreements; however, restructuring the manufacture of research grade marijuana would facilitate responsible, rigorous, clinical research.

EXPAND THE COMPASSIONATE INVESTIGATIVE NEW DRUG (IND) PROGRAM

An alternative, or even concurrent, administrative approach to removing the NIDA monopoly would be to expand the Compassionate Investigative New Drug (IND) Program (commonly called the “Compassionate Use Program”). Beginning with Robert Randall in 1976, the federal government created the program as a means to dispense medical marijuana cigarettes to patients for treatment of medical disorders (in his case, glaucoma).³⁹ The program was expanded through the 1980s to include patients suffering from HIV-related ailments. The patients in the program received cigarettes with marijuana grown at the University of Mississippi, overseen by NIDA. In 1992, the Health and Human Services Secretary decided to stop accepting new patients for the program, citing its lack of medical value.⁴⁰ Ironically, the existence of the program, which was an explicit signal by the federal government that cannabis had (medicinal) value in palliative care, stood in stark contrast to the substance's designation under Schedule I. Although

³⁷ <http://thehill.com/regulation/205080-nih-sees-surge-in-medical-marijuana-research>

³⁸ The PHS review, initiated by President Clinton following the Institute of Medicine's 1999 report on medical marijuana research, was implemented with the perception that marijuana was especially dangerous to the public health and required especially stringent controls.

³⁹ We would like to thank Dr. David Casarett for highlighting some of the details of this program.

⁴⁰ <http://archives.drugabuse.gov/about/organization/nacda/MarijuanaStatement.html>

patients at the time were grandfathered in, the program slowly diminished as patients passed away. NIDA currently distributes marijuana to four people under the program.⁴¹

There are multiple exceptions to regular FDA approval for drugs, including emergency and compassionate use exemptions for single patients. This is usually used in the cases where a patient is ineligible for a clinical trial, or a trial is currently underway, to give individual patients access to new but not-yet-approved drugs. However, the FDA has expressed the need to implement these exceptions in a way that does not “interfere with recruitment for clinical trials needed to support the effectiveness and safety of the drug.”⁴² The FDA has a stated preference for clinical trials, because they “provide appropriate patient protections and potential benefits...and maximize the gathering of useful information about the product, potentially benefiting the entire patient population.”⁴³ This is a wise preference, encouraging new drugs to be administered in a way that ensures the safety of patients and adequate collection of scientific data in order to get the drug (if shown beneficial) to market. It is also a mission statement, if applied to cannabis, that should motivate research and study.

However, reopening the Compassionate Use Program may offer a middle ground between full rescheduling and the status quo. Through NIDA, the FDA could reopen the program to applicants without a prerequisite change in marijuana’s status under the CSA. Reopening the program could come with required data reporting on treatment and effectiveness, as a means to begin more research on marijuana’s medical use. The value of data collected from an expansion of the program is limited, however, because patients are enrolled individually, rather than in a random, controlled trial setting. Ultimately, the Compassionate Use Program would be an insufficient mechanism for approving full-scale clinical trials, but would be a beneficial part of a multi-pronged reform, and may help get medical marijuana and its derivatives (i.e., CBD oil) to patients, while still offering some expansion of the medical field’s understanding of the clinical effects of medical marijuana.

REFORM FDA LICENSES AND CERTIFICATIONS

Even without the NIDA monopoly, marijuana research is by no means simple. As elaborated previously, there is a complex licensing matrix among FDA, DEA, and state laws. While rescheduling is one option for opening up research opportunities, there are multiple, additional reforms to licensure and certifications that could facilitate additional research. Each reform follows different policy making avenues and has varying impacts.

First, Congress can amend the CSA by enacting new standards for licensure and certification around Schedule I substances. These standards would ensure safety and security while meeting the modern-day research needs of individual researchers, institutions or laboratories. Alternatively, legislative reforms could deal with certifications specifically in the context of medical marijuana research. Congress could also work to reform certification processes and requirements through authorization and/or appropriations legislation for FDA and DEA.

For any such reforms, however, Congress (or the executive branch) must ensure that changes to controlled substance certification and licensure rules be steeped in the medical, policy, and public health needs of the scientific community. It should not be driven by political, electoral, or non-technocratic considerations. Other legislative and executive efforts may provide the right type of reforms—those that spur additional, open research into medical

⁴¹ <http://www.cbsnews.com/news/4-americans-get-medical-pot-from-the-feds/>

⁴² <http://www.fda.gov/NewsEvents/Testimony/ucm115209.htm>

⁴³ *ibid*

marijuana—by empowering medical, scientific, public health and other appropriate professionals, rather than non-expert, elected officials.

Congress could pass legislation encouraging FDA and/or DEA to revisit or study their policies regarding licensure and certification for individual researchers and institutions. Joint or independent agency-level study groups could work to ensure that current administrative processes and procedures are consistent with current public policy and public health needs. Such a committee should be sensitive to evidence collected on the topic abroad, experiences with medical marijuana in the states, current state-level medical marijuana policy, and the needs and demands of public health professionals across the U.S. Such a move would lead to reform, but still produce an often sloppy patchwork of individual agency solutions. In one sense, it empowers those with public health and bureaucratic expertise to decide the type and breadth of reform. At the same time, bureaucratic inertia and the cultural biases noted above could still hinder the types of uniform changes that reflect public policy needs.

Similarly, presidential efforts can encourage FDA and DEA to reexamine and study the current state of licensure and certification processes. The president could initiate regulatory processes that push reforms in an effort to meet contemporary public policy needs. Alternatively, like the previous suggestion involving Congress, the president can appoint a study committee to make recommendations to him (or her) and/or to the relevant agencies about the necessary reforms. This approach would similarly empower medical professionals over elected officials. Unlike the congressional study group route, it could avoid some bureaucratic inertia by having White House backing, signaling a presidential priority, and by avoiding some of the inter-branch resistance that can occur when Congress puts direct demands on federal agencies.

ISSUE REGULATIONS OR MEMORANDA FROM RELEVANT AGENCIES ABOUT THE LEGAL BOUNDARIES AROUND CANNABIS

Rescheduling cannabis from Schedule I to Schedule II (or to some other schedule) would be one step in a multi-part reform that would induce expanded research into medical marijuana. Weakening the NIDA monopoly and changing the circuitous nature of DEA and FDA certification and licensure would help as well. However, there still exist multiple legal gray areas and cultural norms that disincentivize researchers from studying medical marijuana.

A more comprehensive reform proposal would include statutory and regulatory guidance that clarifies the federal government's treatment of medical marijuana vis-à-vis the dozens of inter-related issues that compose drug, pharmaceutical, health care, public health, research, tax and spending policy in the United States. Any combination of acts of Congress, executive orders or memoranda, regulations, and agency guidance documents would answer numerous questions that professionals across the U.S. deal with on a daily basis.

Some may argue that doctors, nurses, other medical professionals, hospital and university administrators, institutional review board members, patients, tax attorneys and others exaggerate the “grayness” of the legal gray area that surrounds medical marijuana in the United States. However, when the stakes are high and one's livelihood or even liberty is at stake, erring on the side of caution cannot be seen as an unwise move.

Often, actors are discouraged from engaging in activities surrounding medical marijuana not because of existing information but due to a real lack of information. Public policy is its strongest when information is clear, abundant,

transparent and easily navigable. In the context of federal medical marijuana policy and research, the federal government could do little more to fail in this context.

There are numerous agencies that could enact reforms that would help with specific challenges. DEA can issue guidance on a number of topics. One issue involves practitioners' DEA registration allowing them to issue prescriptions. For most practitioners, this is a fundamental aspect of their profession, and anything jeopardizing their registration status is serious business. Concerns exist about practitioners engaging in medical marijuana research—and even in recommending patients for use of medical marijuana—given the scheduling of cannabis under the CSA. DEA could detail the types of activities vis-à-vis medical marijuana and research that are allowed and disallowed, offering definitive and reasonable boundaries for practitioners.

The Centers for Medicare and Medicaid Services (CMS) could also issue guidelines that will help clarify for medical professionals the federal government's comprehensive position on medical marijuana. Many doctors and hospitals depend on reimbursements from CMS to continue to practice and operate. The agency provides funding for a significant portion of health care in the United States and concerns about continued CMS funding would make any professional gun shy. Fears exist among some that engaging in research related to medical marijuana, recommending medical marijuana to patients and other activities involving the substance in states that allow it for medical purposes can jeopardize CMS funding. Regardless of the legitimacy of those concerns, such concerns exist and introduce uncertainty in the provision of medical services in the U.S. Additional, specific guidance from CMS about the boundaries of medical marijuana policy with respect to agency reimbursement would be useful in assuaging such fears and providing necessary information to practitioners.

Similar institutional concerns exist for not-for-profit entities. Tax-exempt status is designated by IRS to entities that meet specific criteria, and among those criteria is a requirement to operate within the confines of federal law. The Controlled Substances Act and recent U.S. Tax Court rulings create a tax law environment that rightfully worries not-for-profit entities that are interested in supporting, sponsoring, housing or otherwise encouraging research into medical marijuana. Once again, clear guidance around the issue of medical marijuana can help assist entities in understanding the government's position, and if the contents of such guidance allow, can create safe havens for not-for-profit institutions to conduct medical marijuana research.

Finally, the federal government's premier research funding agencies—the National Science Foundation and more importantly NIH—could also issue memoranda that respond to real public policy needs that have emerged around medical marijuana. These funding agencies can make clear that there are substantive and funding priorities that can assist both in the conduct of research on medical marijuana and to expand the depth of expertise within the academy on the topic.⁴⁴ Right now, the meager number of studies that examine medical marijuana creates serious shortcomings in the ability to answer critical questions. These shortcomings exist even as more and more states have approved medical marijuana policy and questions about the clinical use of cannabis grow.

This is far from an exhaustive list of federal entities that are complicit in maintaining a difficult-to-navigate policy environment around medical marijuana. Legislative change would be helpful in expanding research in this area. However, clear leadership from a president committed both to the integrity of research and to answering extant public policy questions is just as important. The president could ask every agency in the federal government to assess whether their mission, jurisdiction and activities relate in any way, direct or indirect, to medical marijuana

⁴⁴ We would like to thank Dr. David Casarett for pointing out this specific challenge.

policy, and if so, require them to review their guidance documents and relevant regulations in order to amend them with any necessary clarity to encourage expanded research.

III. THE POLITICS OF REFORMING MEDICAL MARIJUANA RESEARCH

In the American system—like in any system of government—the best policy is not always the one that is implemented, and the ability to reform a broken policy depends not necessarily on the best idea, but one that can garner sufficient political support. Expanding medical marijuana research by reducing the restrictions that hinder the scientific community not only has political benefits for elected officials, but exists in a unique policy space not overwhelmed by traditional, hyper-partisan, polarization-induced gridlock.

In fact, arguments about expanding opportunities to conduct medical marijuana research has real appeal within Congress, the executive branch, the states, and among 2016 presidential candidates. We will discuss each in turn.

BREAKING DOWN GRIDLOCK

In the current policy making environment, Congress looks more like a war zone than a cooperative, collective body charged with making laws. Party polarization, among elites and in the mass public, has crippled the nation's legislative branch, ensuring that the status quo, rather than reform, almost always wins the day. In most areas of policy and on most issues, the parties consistently disagree with each other, and within parties, there is almost no defection from the party line.

Marijuana is different. The issue makes for strange bedfellows, and the partisanship of an elected official is not wholly determinative of their view on the issue or the likelihood of their disagreement with the other party. Unlike almost any other contemporary political and policy issue, marijuana—and particularly medical marijuana—joins together the most extreme liberals with the most ardent conservatives to form a coalition that also includes moderates. Reform-minded legislators represent rural areas, inner cities, suburbs, large states, small states, both coasts and America's heartland. Yes, there are members of Congress who oppose marijuana reform. Yet, as the past few Congresses have shown, there is often plenty of support to consider and ultimately pass reform-oriented legislation on medical marijuana. In 2015, the Senate passed amendments dealing with multiple facets of the issue—allowing U.S. Department of Veterans Affairs doctors to discuss medical marijuana in states where it's legal, and ensuring legal marijuana businesses' access to banking services, proposals that garnered substantial support from members of both parties. The House has made similar strides, passing an amendment to protect medical marijuana patients from federal prosecution, and similar language has also been approved by the Senate Appropriations Committee. The House has also passed an amendment to protect states that allow CBD oil for the treatment of epilepsy.⁴⁵

As we noted before, however, this paper focuses specifically on medical marijuana. The real story is about liberating the scientific community from legal and bureaucratic inertia that hinders or prevents the conduct of medical research. The proper role of government, we would argue, would be to fund science without imposing answers to scientific questions. Combining an effort to recalibrate government's role in scientific research with one that garners widespread public and legislative support makes for a commonsense policy reform, and an easy sell to the American public.

⁴⁵ We would like to thank the staff at the Marijuana Policy Project for an overview of legislative activity in this area.

Framing is often the currency of political salesmanship, and discussing this issue as one of allowing the medical community to answer critical questions for medical, scientific, and health policy should be effective.

Expanding medical marijuana research is also an odd issue in hyper-partisan Washington, D.C., as it offers a policy space where Congress and the president can agree. In fact, this issue offers common ground between President Obama and his staunchest, most conservative critics in Congress. It is an area where President Obama has indicated his support for a reduced role of government—a perspective that Republicans often accuse the president of being allergic to. It is also an area of health care related policy that Republicans are willing to favor real reform—an action President Obama accuses Republicans of being incapable of.

Empirical questions abound about whether, to what extent, for which conditions, and at what dosing levels marijuana can be used effectively for medicinal purposes. However, medical marijuana has been shown to be an effective treatment for one condition that ails Washington policymakers: gridlock. The politics around medical marijuana policy is increasingly conducive to reform, and the politics should be particularly supportive of expanding research in this area.

2016 POLITICS AND MEDICAL MARIJUANA

While in many respects President Obama has been the most pro-reform president in American history on the issue of marijuana, many in the advocacy community argue he has not done enough to satisfy their needs. A few of the Obama administration efforts have advanced the expansion of medical marijuana research, including the removal of PHS review and increased funding, through NIDA, for expanding the marijuana harvest through the government monopoly. However, as highlighted above, numerous barriers still remain.

As the next president comes to office, he or she will inherit a marijuana policy regime that is inconsistent and often contradictory. It is incumbent on President Obama's successor to introduce some uniformity, discipline, and sensibility to this policy area. Focusing on medical marijuana research would be a good place to begin—and the issue's politics for the next president should be encouraging. In fact, the next president need not wait until January 20, 2017, to pursue and capitalize on this political opportunity; candidates for the presidency should make marijuana work for them.

Right now, with few exceptions, presidential candidates have been vague and evasive on the issue. Some have declined to engage the issue. Others have essentially argued that their policy will reflect the Obama administration's laissez-faire approach. The clearest positions have come from opponents of marijuana reform, like New Jersey Governor Chris Christie, who has argued that he will stop existing state-level marijuana regimes. In the summer of 2015, Christie noted in an interview, "marijuana is against the law in the states and should be enforced in all 50 states...if you're getting high in Colorado today, enjoy it. As of January 2017, I will enforce the federal laws."⁴⁶

For the politics of medical marijuana, these approaches—vague responses or vocal opposition—are serious miscalculations. Any candidate positively disposed toward a pro-reform position on *medical* marijuana can garner profound media and public attention and illustrate a real willingness to engage with a policy community that has largely been marginalized at the presidential level. The issue also provides candidates an opportunity to connect with voters, as a May 2015 Harris poll showed 81 percent of Americans support the legalization of medical marijuana.⁴⁷ By outlining

⁴⁶ <http://www.politico.com/story/2015/07/chris-christie-enforce-marijuana-illegal-2016-120769>

⁴⁷ <http://www.theharrispoll.com/politics/Americans-Ready-for-Legal-Marijuana.html>

a detailed, medical marijuana reform position, a presidential candidate would illustrate boldness and advance policy nuance that has been largely absent from the 2016 campaign thus far. The American public—in an effort to assess and weigh their options—hungers for policy detail from presidential candidates who are often notoriously vague.

Outlining relevant reforms would expand medical marijuana research, assist states in administering their systems, provide additional opportunities for researchers to offer answers to key questions, and help health care providers deliver accurate information to their patients. It also allows a candidate to talk about much more than marijuana. The candidate who opts to offer a detailed research reform agenda can engage broad issues that reflect a comprehensive vision for his or her presidency. A candidate can talk about the role of government, a commitment to funding science, views on healthcare (in an area far less controversial than the Affordable Care Act), the importance and boundaries of federalism, and a multitude of other ideas that tells the American public what type of president that individual may be.

Moreover, the details of such a proposal would illustrate that the candidate has an understanding of the demands of administration. It shows a readiness to lead by reflecting a comprehension not just of desired policy outcomes but of the complexities of the process by which those outcomes come to be.

Particularly among Republicans, such clarity of vision and the engagement of an interesting and cutting-edge area of policy will help a candidate distinguish himself or herself from an overcrowded field, seemingly characterized more by political clones than distinct, independent-thinking politicians. For Democrats, the same primary campaign advantages exist as well, but for a much smaller field.

Candidates are hesitant to take a bold position on (medical) marijuana policy. And frankly, this reluctance is very difficult to understand. Public support for medical marijuana reform is quite high across the country and at the state-level. Multiple polls put the national support for physician-prescribed marijuana between 70 and 80 percent approval.⁴⁸ Polling suggests that in most states—even the most conservative states—support for legalized medical marijuana is at least two to one, and polling at rates of 80 percent or higher in swing states like Ohio, Iowa, Florida, and Virginia.⁴⁹ Medical marijuana also polls favorably in Pennsylvania, North Carolina, and Wisconsin.⁵⁰

Yet, candidates are meek on the issue. Oddly, they are comfortable or even eager to take bold positions on much more controversial topics including the Affordable Care Act, entitlement reform, foreign intervention, climate change, and immigration policy, to name a few. But the medical marijuana reform embraced by the public seems to scare candidates. Medical marijuana reform should be an easy one for a candidate seeking to connect with prospective voters and the expansion of medical research in the area should be an even easier consideration.

As the next president comes to office, he or she will inherit a marijuana policy regime that is inconsistent and often contradictory. It is incumbent on President Obama's successor to introduce some uniformity, discipline, and sensibility to this policy area.

⁴⁸ <http://www.thirdway.org/report/the-marijuana-middle-americans-ponder-legalization> and <http://www.foxnews.com/politics/interactive/2013/05/01/fox-news-poll-85-percent-voters-favor-medical-marijuana/>

⁴⁹ Quinnipiac polls. <http://www.quinnipiac.edu/news-and-events/quinnipiac-university-poll/2016-presidential-swing-state-polls/release-detail?ReleaseID=2183>

⁵⁰ Ibid., and <https://ncnorml.files.wordpress.com/2015/02/poll-2015-ppp-north-carolina.pdf>

Discussing marijuana policy also allows candidates to engage in outreach to multiple different groups using varied messaging strategies. Presidential campaigns are often about honing messages in ways that have the biggest impact among the most diverse group of people, and every candidate who refuses to engage marijuana policy misses a political and electoral opportunity that shows political naïveté, rather than political savvy.

Beyond the political benefits that marijuana policy can provide to 2016 presidential candidates, there is a serious policy demand that should incentivize candidates to take clear positions on this complex issue. The next president has no choice but to deal head on with marijuana in the states, and expectations will be high that they provide or pursue some type of federal remedy to the current disjointed system. Whether it is a prohibitionist approach trumpeted by the nation's remaining drug warriors or a reform-oriented solution advanced by marijuana supporters and states that have legalized medical and recreational marijuana, some kind of change is necessary. The middle ground—the Obama administration approach—may be a temporary remedy but is by no means a tenable, long-term solution to this public policy question.

Finally, in the context of expanding medical marijuana research, there is a real opportunity for the next president early in his or her administration. Given public and congressional support for medical marijuana, the next president can use this issue as a springboard for overcoming gridlock in the early days of the new presidency. As the public and media look to the first 100 days to see what a new president can get done, medical marijuana research reforms may be one such policy change.

The opportunity would exist for the new president to build and maintain relationships with both parties in Congress, with the hope of actually working together for the next four or eight years. In the wake of an Obama presidency characterized by gridlock, inter-party strife and intra-party unhappiness with a legislatively unengaged chief executive, the early pursuit of a proposal such as expanding medical marijuana research—a reform with bipartisan support—would be a strong signal from a new president ready to turn a leaf on the dysfunction and distrust of the prior eight years.

POT POLITICS AND THE STATES

When it comes to marijuana policy, states are begging the federal government for new laws, revised regulations, and improved guidance. As legislatures and voters approve reforms that legalize medical (and in some cases recreational) marijuana, states were (and are) left to implement laws that the public demands and that the federal government, in some contexts, prohibits. This scenario creates a bizarre legal environment that complicates not just public policy but our understanding of federalism.

For state leaders, particularly those in the dozens of states that have legalized marijuana in some form, the bipolar nature of federal marijuana policy is not just confounding, but creates risks to public health and public safety. Responsible policy would speak in one voice to overcome the disjointed status quo that makes the public understanding and the government implementation of law more difficult.

In addition, removing the limitations that hinder medical marijuana research will motivate states to fund, support, and encourage it. Under current policy, there are cultural norms, legal concerns, and a general lack of knowledge about how federal officials may react to the initiation of cannabis-related medical research projects—especially those funded by sources other than the federal government. The U.S. government has an opportunity to enact reforms that remove those questions and in their place provide a clear, robust, and consistent policy toward research into

medical marijuana. Until that time, state institutions—laboratories, universities, hospitals, and all other entities that depend in part on federal funding, on federal certification, or are subject to federal regulatory environments—may be hesitant to condone such research.

Current medical marijuana policy is not static. Every year, more states are considering and expanding policy to legalize medical marijuana.⁵¹ As each does, they have only existing state systems to consider when designing the structure, boundaries, and administrative procedures of their own policy experiment. There are real benefits to be had when the architects of public policy have better information, and expanding research will help future states that consider such reforms.

Take for example, Colorado Gov. John Hickenlooper, who frequently discusses the depth of the challenge he and his administration faced when voters approved Amendment 64, legalizing recreational marijuana.⁵² With no existing states with similar systems and meager information about what a legal and regulatory framework should look like, the implementation of this reform was tremendously risky. Ultimately, the Hickenlooper administration fared quite well in this arena, but was not a safe bet in November 2012. In the context of recreational marijuana, that policy blindness is a bit understandable. When it happens in the context of medical marijuana, there is no excuse for the dearth of scientific information and no one is more to blame for that shortcoming than the United States government.

What's more, expanding research should be a cause championed by the most passionate pro-marijuana advocates as well as the most ardent drug warriors—and everyone in between. If you believe that cannabis is an elixir that can be used to treat a variety of ailments with very few side effects or risks of overdose, then you should support the scientific community validating your perspective. Alternatively, if you believe cannabis is a gateway drug, inappropriate for pharmaceutical (or any) use because it is a source of addiction and has no medicinal value, then you should also support a scientific validation of your views. Finally, if you believe cannabis' medicinal value is an open, unanswered, empirical question, then you should embrace the medical community's ability to provide definitive evidence.

Regardless of one's perspective and regardless of the status of medical marijuana in a given state, there is ample reason, given the realities of current and future state-level policymaking, to encourage the federal government to break down the barriers currently limiting research in this area.

For medical marijuana policy broadly and the expansion of medical research specifically, there are numerous opportunities that have political benefits for Congress, President Obama, and the 2016 presidential candidates. Elected officials—and those running for office—who seize such an opportunity will highlight how much public opinion and the policymaking environment has changed in the United States.

⁵¹ In fact, the National Conference of State Legislatures recently approved a resolution calling for an end to federal interference in state marijuana laws. (See: http://www.ncsl.org/documents/standcomm/sclaw/Marijuana_Policies_Federal_Interference.pdf)

⁵² <http://www.brookings.edu/research/reports/2014/07/colorado-marijuana-legalization-succeeding>; <http://www.brookings.edu/events/2015/02/20-good-governance-states-beshear-hickenlooper>

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IV. CONCLUSION

Marijuana policy has shifted rapidly in the U.S. in the last 10 years. Public demands, especially for increased medical research, have run head on into a system of overlapping and complicated federal law. The scheduling of marijuana under the CSA is one part of this layered system that impedes legitimate medical research on the benefits—and harms—that marijuana can have for a variety of ailments. But rescheduling is by no means the only barrier. Removing the DEA-mandated NIDA monopoly on production of marijuana for research, issuing agency guidance, expanding the compassionate use program, and reforming license and registration requirements would all go a long way to improve the scientific community's capacity and ability to study marijuana for medical use. Thousands of Americans use marijuana for medical purposes, and many do so legally in 23 states and the District of Columbia. Yet, Congress and federal agencies continue to impede clinical research on the appropriate usage of marijuana. It's time to stop letting outdated policy prevent the scientific community from advancing knowledge and ensuring that patients and practitioners understand the benefits and risks of medical marijuana.

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APPENDIX: PATHS TO RESCHEDULING

